



# Sham IND's and the Hatch-Waxman Act of 1984

## Citation

Sham IND's and the Hatch-Waxman Act of 1984 (2003 Third Year Paper)

## Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8846792>

## Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

## Share Your Story

The Harvard community has made this article openly available.  
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

# Sham IND's and the Hatch-Waxman Act of 1984

S. Jorgenson

Class of 2003

Harvard Law School

Food and Drug Law

Professor Hutt

2003

**\* This paper is submitted in satisfaction of the course requirement and the third year written work requirement.**

## Abstract

The Hatch-Waxman Act of 1984 created an exemption to patent infringement for activities that constitute uses reasonably related to the process of seeking FDA approval for a drug. Although intended to help generic drug manufacturers enter the market more quickly, the courts have interpreted this exemption in such way that they have created a loophole that allows individuals and corporations to profit from activities that would otherwise constitute patent infringement. As long as these activities could arguably be connected to one of the many stages in the FDA approval process, a potential infringer is shielded from an infringement suit. The current state of the law is not the balance Congress sought to strike between patent holders, their competitors, and researchers.

## Introduction

By 1984, Congress was increasingly concerned with the runaway costs of prescription drugs. A recent Federal Appeals Court decision had held that the holders of drug patents could prevent competitors from beginning the process of applying for FDA approval of their generic substitutes until the relevant patents expired. Since the FDA approval process took quite a bit of time, the holders of drug patents received a de facto extension of the term of their patents until the generic alternatives could be approved. Without competition from generic drugs, manufacturers of patented drugs could keep prices high.

The Hatch-Waxman Act of 1984 sought to both streamline the approval process for generic drugs and also end the de facto patent term extension by allowing generic drug manufactures to engage in the activities necessary to

secure FDA approval before the patents expired. This way, the generic substitute could enter the market as soon as the relevant patents expired.

The language of the statute implementing this goal is potentially broader than the goal itself. Companies began to push the limits by engaging in activities with purposes unrelated to or secondary to securing FDA approval. Early court cases strictly limited the types of activities allowed under the statute. More recently, however, the courts have adopted a more broad approach that does not look to the purposes of the activities in question, but to the activities themselves. Any activity that arguably falls within one of the stages of the FDA approval process is not patent infringement.

This broad interpretation of the statute has opened the door to the possibility of abuse. Anyone conducting a clinical trial under the FDA's regulations is arguably shielded from patent infringement suits. However, investigators conduct clinical trials under FDA supervision for a wide variety of reasons, many not for the purpose of seeking FDA approval, and many having nothing to do with generic substitutes. Thus this broad interpretation exempts infringing activity that Congress did not express an intent to exempt.

Aside from being inconsistent with Congress' intent, this broad interpretation of the Hatch-Waxman Act undermines the patent system's ability to promote scientific progress by preventing patent holders from realizing the rewards of their inventions.

## **The Problem**

### **Part 1: The Limited Grant of Exclusivity**

Article 1, Section 8, Clause 8 of the United States Constitution empowers Congress to “promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” The useful arts are promoted by a bargain the government makes with inventors. In exchange for the financial rewards that accompany the exclusive right to an invention, the inventor discloses to the world how his invention works. The inventor’s grant of exclusive rights is only for a limited time, so that at the end of that time his invention passes into the possession of the public. The Constitution leaves to Congress the task of deciding the length of this period of exclusivity. This enables Congress to decide what period of time best promotes the progress of discovery by adequately rewarding inventors while making their inventions available to benefit the public as soon as possible.

Since June 8, 1995, the term of a utility patent issuing from an application filed in the United States Patent and Trademark Office runs from the date a patent is granted until twenty years from the date the application was filed.<sup>1</sup> At the time of the Hatch-Waxman Act of 1984,<sup>2</sup> the term of a patent began the date a patent was granted and ended seventeen years later. Patents filed before June 8, 1995, but still in force as of that date have a term equal to the longer of the term calculated using the “twenty years from filing date” method or the “seventeen years from issuance” method.<sup>3</sup>

---

<sup>1</sup>35 U.S.C. § 154.

<sup>2</sup>Pub. L. 98-417, 98 Stat. 1985 (1984).

<sup>3</sup>35 U.S.C. § 154(c).

## Part 2: Drugs and Medical Devices<sup>4</sup> May Not be Sold in the U.S. without FDA Approval

21 U.S.C. § 355(a) provides that “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.” Subsection (b) deals with the procedures required by the Food and Drug Administration (FDA) for a New Drug Application (NDA). Subsection (j) deals with the procedures for an Abbreviated New Drug Application (ANDA). ANDA's are generally used for drugs or active ingredients that are similar or equivalent to those already approved by the FDA pursuant to an NDA, which are often called pioneer drugs. The ANDA procedure is most often used by manufacturers of generic drugs. The requirements under an ANDA are less strict and less time consuming than under an NDA, which is expected since another manufacturer has presumably shown that the drug meets the FDA's requirements.

In order to submit an application for approval of a new drug, the FDA requires the manufacturer to show that the new drug is safe and effective.<sup>5</sup> This process requires many steps. The first stages of testing are normally done in animals. Once the pharmacology,<sup>6</sup> pharmacokinetics,<sup>7</sup> and toxicology<sup>8</sup> of the drug in animals are known, investigators may decide that further testing in humans (clinical trials) appears to be safe and might produce beneficial results.

To begin testing in humans would require the introduction of an unapproved drug into interstate commerce, which would violate 21 U.S.C. § 355(a). The statute provides an exception to many of the requirements of § 355 for drugs used for research in § 355(i). The FDA has set up the Investigational New Drug (IND) process to regulate

---

<sup>4</sup>This paper generally approaches the issue from the point of view of drugs, but the Hatch-Waxman Act has been held to apply to medical devices as well. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). The procedures for gaining FDA approval of medical devices are roughly analogous to those for drugs; at least as far as 35 U.S.C. § 271(e)(1) is concerned.

<sup>5</sup>21 U.S.C. § 355(d).

<sup>6</sup>Pharmacology refers to the properties of a drug that make it medically effective.

<sup>7</sup>Pharmacokinetics refers to the way in which a drug is absorbed, processed, and eliminated by the body.

<sup>8</sup>Toxicology refers to the extent to which a drug is poisonous and the effect of that poison on the body.

the use of drugs for testing in humans.

The FDA's regulations divide testing in humans into three phases; Phase 1, Phase 2 and Phase 3.<sup>9</sup> An investigator generally submits an IND application for each new study.<sup>10</sup> Phase 1 studies include the initial introduction of the drug into humans.<sup>11</sup> These studies are used to judge the pharmacology, pharmacokinetics, and toxicology of the drug in humans.<sup>12</sup> The side effects associated with increasing dosage are also evaluated.<sup>13</sup> The information learned from Phase 1 studies is used to design Phase 2 studies so that the Phase 2 studies will produce scientifically valid results.<sup>14</sup>

Phase 2 studies are controlled studies conducted to evaluate the effectiveness of the drug for a particular indication in patients with the disease being studied.<sup>15</sup> These studies evaluate the short-term side effects and risks associated with the drug.<sup>16</sup> They include a smaller number of people than a Phase 3 study, typically no more than several hundred subjects.<sup>17</sup>

Phase 3 studies are expanded studies, usually performed after preliminary evidence that the drug is effective is obtained.<sup>18</sup> They gather the information needed to make an overall risk-benefit judgment regarding the drug.<sup>19</sup> These studies often include several thousand subjects.<sup>20</sup> Phase 3 studies are often referred to as "pivotal" studies because the information they generate provides a basis for the FDA's decision on whether to approve an NDA. Although not required by statute or regulations, most drugs undergo two pivotal studies to generate the information needed for a decision by the FDA on whether to approve them.<sup>21</sup>

---

<sup>9</sup>21 C.F.R. § 312.21.

<sup>10</sup>*Id.*

<sup>11</sup>21 C.F.R. § 312.21(a).

<sup>12</sup>*Id.*

<sup>13</sup>*Id.*

<sup>14</sup>*Id.*

<sup>15</sup>21 C.F.R. § 312.21(b)

<sup>16</sup>*Id.*

<sup>17</sup>*Id.*

<sup>18</sup>21 C.F.R. § 312.21(c)

<sup>19</sup>*Id.*

<sup>20</sup>*Id.*

<sup>21</sup>See Peter B. Hutt & Richard A. Merrill, *Food and Drug Law, Cases and Materials* 527 n.2 (2nd ed. 1991).

As one can imagine, all of these steps take time and must be done one after the other, not at the same time, since each step requires information from the previous step. The Pharmaceutical Manufacturers Association estimates that the average drug takes twelve years to go through this process.<sup>22</sup> In 1980, the House Subcommittee on Science, Research, and Technology estimated the time to be 7-13 years.<sup>23</sup> A generic equivalent under the ANDA process takes less time because much of the same testing is not required. However, the manufacturer must show that the generic equivalent is bioavailable<sup>24</sup> and bioequivalent<sup>25</sup> to the already-approved drug.<sup>26</sup> These showings may also require extensive testing lasting several years.

## The Patent Term Distortion

The mere fact that the FDA approval process takes some time distorts the term of a patent. Sometimes this distortion has the effect of effectively shortening the period of enforceability of a patent. This can be seen when an inventor invents a new drug and then files a patent application. The day he files that application, the clock begins to run on his patent term and if issued, that patent will expire twenty years after he filed the application. Before he can commercially exploit his invention, however, the inventor must get the FDA to approve the use of the drug. Once the patent issues, every day that the inventor must wait for FDA approval is another day of his patent term that is lost. Since the FDA approval process can take 7-10 years or more<sup>27</sup>, the term of the patent

---

<sup>22</sup>See [http://www.allp.com/drug\\_dev.htm](http://www.allp.com/drug_dev.htm).

<sup>23</sup>Report of the Subcommittee on Science, Research and Technology of the House Committee on Science and Technology, 96th Congress, 2nd Session (1980).

<sup>24</sup>Bioavailability refers to the extent a drug moves through the body and becomes available at the site of drug action. See 21 C.F.R. § 320.1.

<sup>25</sup>Bioequivalence refers to drugs that are absorbed by the body in the same general manner. See 21 C.F.R. § 320.1.

<sup>26</sup>21 U.S.C. § 355(j)

<sup>27</sup>See *Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 864 (Fed. Cir. 1984).



may be effectively cut in half or worse.

The inventor could try to minimize this loss of patent term by delaying his filing date, but this presents several risks. The inventor has one year from the date the invention becomes public due to a public use, offer for sale, or printed publication to file for a patent,<sup>28</sup> whether the inventor authorized the publication of his invention or not. If another person filed for a patent for the same invention before the inventor filed, the burden of showing prior invention would be on the inventor.<sup>29</sup> The inventor may intend to file overseas, and most countries award patents to the first entity to file for a patent, not the first to invent. But once the inventor files overseas, he has only the longer of one year or until the foreign patent issues to file in the U.S.<sup>30</sup>

Such delays in filing are inconsistent with the goals of the patent system favoring prompt public disclosure of inventions.<sup>31</sup> The Hatch-Waxman Act dealt with this problem by providing for patent term extensions for unavoidable delays due to the FDA approval process.<sup>32</sup>

The FDA approval process might also distort the term of a patent by effectively lengthening it. This situation arises near the end of the term of a patent for a drug. Once the patent expires, other drug companies have the right to make and sell the patented drug or a drug that contains the patented ingredient (often referred to as a generic substitute) under the patent laws. However, this other drug company must get FDA approval in order to sell its version of the drug. Since any use of the patented drug would be patent infringement, the other company cannot begin the process of obtaining FDA approval until the day the patent expires. The entire period from the end of the patent term until the generic drug is approved is a period of exclusivity for the patentee since the patentee is the only one able to make and sell the drug. This period is an effective lengthening of the patent

---

<sup>28</sup>See 35 U.S.C. § 102(b).

<sup>29</sup>See 35 U.S.C. § 102(e).

<sup>30</sup>See 35 U.S.C. § 102(d).

<sup>31</sup>See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998).

<sup>32</sup>See 35 U.S.C. § 156.

term.

## The Need for § 271(e)(1) – Roche

Before 35 U.S.C. § 271(e) was enacted, a generic drug manufacturer who made, used, or sold a patented drug infringed the patent. Congress currently defines infringement by declaring, “[W]hoever without authority makes, uses, offers to sell, or sells any patented invention within the United States . . . infringes the patent.”<sup>33</sup> Any one of these acts, even taken alone, constitutes infringement.<sup>34</sup>

A manufacturer seeking to market a new drug or generic equivalent of a current drug needs to submit an NDA or ANDA and in order to do so, would have to have conducted the various applicable studies discussed above. However, the manufacture of a drug intended to be used in any kind of study would be infringement. Likewise, the actual use of a patented drug in an animal or clinical study would constitute infringement. Selling the patented drug to those who are actually doing or participating in any studies would also be infringement, even if the drug were sold at cost. Thus a manufacturer who wanted to submit an NDA or ANDA would have to wait until the day after any patent expired to begin the process that leads up to its ability to do so.

The party accused of infringement (the defendant) in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* tried to

---

<sup>33</sup>35 U.S.C. § 271(a)

<sup>34</sup>See *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964).

argue that the so-called “Experimental Use” exception applied to its activities.<sup>35</sup> The defendant Bolar decided it wanted to market a generic equivalent to patentee Roche’s drug Dalmane once Roche’s patent expired.<sup>36</sup> About six months before the patent expired, Bolar obtained from a foreign manufacturer<sup>37</sup> five kilograms of the drug’s active ingredient to use to make dosage form capsules, which it would “use to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies necessary for a New Drug Application to the United States Food and Drug Administration (FDA).”<sup>38</sup> Roche sought to enjoin Bolar from using the patented drug for any purpose whatsoever until the patent expired.<sup>39</sup>

The Court of Appeals for the Federal Circuit<sup>40</sup> framed the legal question simply: “[D]oes the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable?”

The court answered in the affirmative.

Bolar tried to argue that the so-called “Experimental Use” exception should be applied to its activities. There has never been such an exception provided for by statute. The origin of this doctrine appears to be an opinion written by Supreme Court Justice Story while riding circuit in 1813. The doctrine created an exception for the use of a patented machine for non-economic purposes. As Justice Story wrote, “It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”<sup>41</sup> By 1890, the principle made its way into the authoritative treatise by W. Robinson:

---

<sup>35</sup>733 F.2d 858 (Fed. Cir. 1984).

<sup>36</sup>*Id.* at 860.

<sup>37</sup>Since Roche, Congress has amended 35 U.S.C. § 271(a) to include within in the definition of infringement one who imports into the United States any patented invention during the term of the patent.

<sup>38</sup>Roche, 733 F.2d at 860.

<sup>39</sup>*Id.*

<sup>40</sup>The Court of Appeals for the Federal Circuit has exclusive jurisdiction to hear patent appeals from the district courts and from proceedings in the U.S. Patent Office.

<sup>41</sup>*Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of pecuniary character.... Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimenter, or if the experiments are conducted with a view to the adaptation of the invention to the experimenter's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.<sup>42</sup>

Since the use in Roche was clearly “for the convenience of the experimenter” and was conducted in order to commercially exploit the patented product in the future, the experimental use doctrine did not apply. The court held, “We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes.”<sup>43</sup>

Bolar then tried to argue that the court should create a “public policy” exception for its conduct. Bolar pointed to the effective patent term extension created by the FDA approval process as discussed above and characterized it as a conflict between the patent statute and the FDA statute. The court did not view this as a conflict between statutes. “[W]hen two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.”<sup>44</sup> The court pointed out that because “[L]aws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject, we must presume Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it.”<sup>45</sup> The court practically invited Congress to take up the issue. “We decline the opportunity

---

<sup>43</sup>Roche, 733 F.2d at 863.

<sup>44</sup>Id at 864 [citations omitted].

<sup>45</sup>Id. [citations omitted].

... to engage in legislative activity proper only for the Congress.”<sup>46</sup>

#### The Reversal of Roche: § 271(e)(1)

Part of the Hatch-Waxman Act contained Congress’s response to the invitation to reverse Roche. It did so by declaring certain acts to be not infringement, where such acts would otherwise be considered infringement. The result is codified in 35 U.S.C. § 271(e)(1) which states:

It shall not be an act of infringement to make, use, offer to sell, or sell with the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs . . . .

The House Report on the proposed legislation specifically cites the effective extension of the patent term in light of the length of the FDA approval process and the recent decision in Roche as the motivating factor for the provision.<sup>47</sup> Prevention of such experimental activity “would extend the patent owner’s commercial exclusivity beyond the patent expiration date.”<sup>48</sup>

The report stated that to best fulfill the purpose of the patent clause in the Constitution,<sup>49</sup> the limited time granted to a patentee “[S]hould be a definite time and, thereafter, immediate competition should be encouraged. Congress’s vision was that since the FDA approval process could be started before the patent expired, this would result in the effective approval date of a drug being “the expiration date of the valid patent covering the original product.”<sup>50</sup> Thus economic competition could begin the day the patent’s exclusive grant expired.

#### Judicial Interpretation of § 271(e)(1)

With a new statute in place, it was now up to the courts to decide what that statute meant<sup>51</sup> as various cases

---

<sup>46</sup>Id at 863-864.

<sup>47</sup>H.R. Rep. No. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

<sup>48</sup>Id.

<sup>49</sup>Article 1, Section 8, Clause 8.

<sup>50</sup>H.R. Rep. No. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

<sup>51</sup>See *Marbury v. Madison*, 5 U.S. 137, 1 Cranch 137, 177, 2 L. Ed. 60 (1803) (it is “the province and duty of the judicial

arose in which parties accused of infringement sought to exempt their activities under § 271(e)(1). A quick reading of the language of § 271(e)(1) reveals that the language Congress chose is potentially broader than the problem it was intended to solve. Deciding how much broader was up to the courts.

## Scripps

One of the first cases to deal with the breadth of § 271(e)(1) was *Scripps Clinic & Research Foundation v. Genentech, Inc.*<sup>52</sup> in 1987. That case involved an infringement action over Human Clotting Factor VIII:C. The plaintiff developed a process for purifying and concentrating Factor VIII:C from human and animal blood plasma and patented the process, the product, and the product made by the process.<sup>53</sup> The defendant Genentech developed a process for making Factor VIII:C using recombinant DNA technology. Genentech, intending to market its Factor VIII:C in the United States, submitted an ANDA to the FDA in an attempt to get FDA approval. Genentech also applied for a European patent, worked on developing a process to commercially manufacture Factor VIII:C on a large scale, and sold some of its Factor VIII:C to one of its partners for its use. Because Genentech was using and selling the patented product, it was found to infringe the plaintiff's patents.

Despite these facts, Genentech moved for summary judgment of no infringement on the grounds that its activities were covered by § 271(e)(1). Genentech argued that although not all of its activities were done solely for department to say what the law is.”).

<sup>52</sup>666 F. Supp. 1379 (N.D. Cal. 1987), modified on other grounds 678 F. Supp. 1429 (N.D. Cal. 1988), aff'd in part, rev'd in part, vacated in part, remanded on other grounds, 927 F.2d 1565 (Fed. Cir. 1991).

<sup>53</sup>Product-by-process claims cover a product, but only if the product is made by the process described in the claim. Thus an identical product made by a different process would not infringe the product-by-process claim. See, e.g., *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 310 (1884).

FDA approval, all bore “some reasonable relationship to such purposes and hence [were] noninfringing under § 271(e)(1).”<sup>54</sup>

The court was confronted with interpreting the phrase “solely for uses reasonably related to the development of information under a Federal law...” in § 271(e)(1). One possible interpretation would be that “solely” applied literally to the word “uses.” Under such an interpretation, only uses whose purposes were expressly related to the FDA approval process would qualify for exemption under § 271(e)(1). Another interpretation, the one urged by Genentech, would be that any use reasonably related to the FDA approval process would be exempted, even if such use had other purposes or goals.

The court chose the first interpretation. The court reasoned that Genentech’s interpretation would, “in effect, eliminate the express statutory limitation ‘solely for’ and thereby immunize any use of a patented invention so long as some aspect of that use is reasonably related to FDA testing.”<sup>55</sup> The court found that this reading defied “the plain mandate of the statute and the intent of Congress.”<sup>56</sup>

The court used the history of the statute to support its reasoning. The court noted that the § 271(e)(1) was passed in response to Roche and that the use found to constitute infringement in Roche was “limited” to “testing and investigation strictly related to FDA drug approval.”<sup>57</sup> There was no reason to believe that Congress intended to provide broader protection.

The court also pointed to the comments in the House Report which indicated that the authors intended the exemption to be narrow. The comments provide that “a generic drug manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.”<sup>58</sup> The House Report went further by stating that “the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can

---

<sup>54</sup>Scripps, 666 F. Supp. at 1396.

<sup>55</sup>*Id.*

<sup>56</sup>*Id.*

<sup>57</sup>Roche, 733 F. 2d. at 861.

<sup>58</sup>H.R. Rep. No. 98-857(II), at 5 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2689.

establish the bioequivalency of a generic substitute.”<sup>59</sup>

The court concludes, “Even if the uses . . . were reasonably related to meeting FDA requirements, they certainly were not solely related to that purpose. These sales and uses [serve] multiple purposes unrelated to meeting FDA requirements [and] clearly lie beyond the protection of § 271(e)(1).”<sup>60</sup>

Such an interpretation is consistent with the history and stated purpose of the statute, and carves out a quite narrow exemption to infringement. It is not, however, the only reasonable interpretation of the statute’s meaning.

## Intermedics

Four years later, the same District Court as *Scripps* (Northern District of California) decided *Intermedics, Inc., v. Ventritex, Inc.*<sup>61</sup> and reached a starkly different result. In *Intermedics*, the defendant Ventritex had developed an implantable defibrillator that it intended to market commercially. Intermedics had obtained seven patents that it argued covered the product developed by Ventritex. Ventritex began clinical trials of the device believing it was immune from claims of infringement under § 271(e)(1). Intermedics sued for infringement and Ventritex moved for summary judgment on the grounds that its activities were protected by § 271(e)(1). Intermedics moved for summary judgment on the theory that § 271(e)(1) did not apply because the defendant intended to commercialize its product prior to the expiration of Intermedics’ patent.

The court ruled for the defendant Ventritex on both motions. First the court addressed the argument that Ventritex’s intent to commercialize its infringing device before the patent expired brought its activities outside the “safe harbor” of § 271(e)(1). Then the court addressed Ventritex’s argument that its activities fell within the

---

<sup>59</sup>H.R. Rep. No. 98-857(II), at 8 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2692.

<sup>60</sup>*Scripps*, 666 F. Supp. at 1396.

<sup>61</sup>755 F. Supp. 1269 (N.D. Cal. 1991), aff’d without opinion, 991 F. 2d. 808 (Fed. Cir. 1993) (non-precidential).



“safe harbor” of § 271(e)(1) as a matter of law.

#### Plaintiff Intermedics’ Motion for Summary Judgment that § 271(e)(1) does not Apply

Intermedics first argued that Congress’ intent should be used to interpret § 271(e)(1); an argument that proved persuasive in *Scripps*. Since “a reason Congress passed § 271(e)(1) was to prevent a patent holder from obtaining the de facto extension of its patent-monopoly which would otherwise occur if the alleged infringing manufacturer had to wait until the expiration of the patents-in-issue to start the investigations necessary to secure FDA approval,”<sup>62</sup> Intermedics argued that the only permissible use of the patented product was that which resulted in the infringer entering the market after the patent expired.

The court rejected this argument on several grounds. One ground had to do with the difficulty of bringing the concept of intent into the inquiry. The court first notes the difficulty of ascertaining subjective intent in a “natural person,” much less the difficulty of “searching for such a thing in a corporate body or other business organization.”<sup>63</sup> Furthermore, it would be difficult to argue that a defendant’s activities were outside of § 271(e)(1) if the defendant did not actually commercially market its infringing product before the patent expired. Even if a particular defendant intended to commercially market his device before another party’s patent expired and then changed its mind, the activities in which it engaged in order to get FDA approval would be indistinguishable from those engaged in by a party who did not intend to commercially market its device before the other party’s patent expired. As the court points out, “Surely Congress was not concerned about clearing certain ‘unacceptable’ thoughts or hopes or visions out of certain persons’ minds.”<sup>64</sup>

---

<sup>62</sup>Id at 1273.

<sup>63</sup>Id.

<sup>64</sup>Id.

Had the court stuck with this argument alone, it could have ruled on the plaintiff's motion and not needed to further analyze the issue. Instead the court chose to address the plaintiff's arguments with respect to Congress's intent and found a totally different intent than the court in *Scripps*. Here, the court found that Congress' primary concern "was not with the de facto length of patent holders' rights."<sup>65</sup> Instead, Congress' primary concern was "to create a legal environment that would enable new, medically beneficial, cost-competitive products to reach the general marketplace in meaningful volume just as soon as the undistorted operation of the patent laws would permit."<sup>66</sup>

The difference, the court says, is an emphasis on the positive instead of the negative.<sup>67</sup> The court believed that it was Congress' intent that the safe harbor of § 271(e)(1) would be available to "every party who might be in a position to enter the general market place when the relevant patents expire."<sup>68</sup> (emphasis added) The court contrasts this with what it characterizes as the plaintiff's view that this protection would be available "only to those parties who would enter the general marketplace after the relevant patents expired."<sup>69</sup> (emphasis added) Put another way, Congress wanted to protect research and investigational activities that might lead to a party entering the market, whether or not the party actually does enter or is even sure it will try.

While this is certainly true, it does not fully address the plaintiff's argument. What if a party was engaged in activities that might fall under § 271(e)(1), but that party was engaged in those activities for purposes that did not involve obtaining regulatory approval after the patent expired? Clearly, whether a party ultimately decides to seek regulatory approval to market its product is not determinative. The House Report states, "A party which develops such information, but decides not to submit an application for approval, is protected as long as the development was done to determine whether or not an application for approval would be sought."<sup>70</sup> It would seem that if

---

<sup>65</sup>*Id.*

<sup>66</sup>*Id.*

<sup>67</sup>*Id.* at 1274.

<sup>68</sup>*Id.*

<sup>69</sup>*Id.*

<sup>70</sup>H.R. Rep. No. 98-857(I), at 45 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2678.

a party could show that a potential infringer had no intent to seek FDA approval after the patent expired, the infringer's activities would not be covered by § 271(e)(1). Such a showing of the intent of a corporation might be difficult, but this relates to the first ground the court used to reject the plaintiff's argument as discussed above. By going further, the court has broadened the scope of § 271(e)(1) protection to include activities which may not be related to seeking FDA approval as long as a party can argue that such activities could be.

In order to rebut the plaintiff's suggestion that the statute's focus is on activities done with the purpose of seeking FDA approval, the court must be able to disregard part of the House Report that says "a generic drug manufacturer may obtain a supply of a patented drug product during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval."<sup>71</sup> (emphasis added) To do so, the court declares that much of the legislative history relied on in *Scripps* deals only with drugs and does not apply to medical devices. The court notes that with generic drug manufacturers, the testing done during the life of the patent involves bioequivalency, which necessarily uses the patented drug because the generic drug is compared to the patented drug in the tests. The court distinguishes the medical device approval process because it points out that there is no analogous ANDA process involving bioequivalency for devices. A manufacturer must test his device and show it is safe and effective even if a similar device is already approved. The court points out that because the potentially infringing manufacturer is not actually using the patentee's device, it may not believe that it is infringing at all since it may not believe that its device infringes the patent. If a potentially infringing manufacturer does not believe it is infringing, then it would have "no reason to wait until the expiration of the allegedly infringed patent to begin commercial marketing."<sup>72</sup>

This reasoning seems flawed to in several respects. First of all, there is a path similar to an ANDA for medical devices. There are two general ways in which a medical device may be lawfully introduced into commerce.<sup>73</sup> The

---

<sup>71</sup>H.R. Rep. No. 98-857(II), at 5 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2689.

<sup>72</sup>*Id.*

<sup>73</sup>There is also a third way, involving reclassification from a Class III device to a Class I or II device under § 513(f)(2) of the Food,

first is by submitting a Pre-Market Approval (PMA) application that is then approved by the FDA.<sup>74</sup> This process is similar to the NDA process. The other general way to gain approval is by submitting a Pre-Market Notification (PMN) under § 510(k) of the Food Drug and Cosmetic Act of 1938 (FDCA) for a device that is substantially equivalent to a device that was on the market before the 1976 Amendments to the FDCA (called a “preenactment device”). “Substantial Equivalence” is defined in §§ 513(f)(1) and 515(b)(1) of the FDCA. The FDA has also taken the position that a new device may claim substantial equivalence to a device on the market that claimed substantial equivalence to a preenactment device.<sup>75</sup> This concept is known as “piggybacking” and can result in chains of claims of substantial equivalence. This second route, by which a device claims substantial equivalence to a preenactment device, accounted for the way in which more than 98 percent of new medical devices entered the market between 1976 and 1991.<sup>76</sup> In the abstract, a potentially infringing manufacturer would need to “use” an approved, patented device to compare with its own device in order to claim substantial equivalence in the same way that a generic drug manufacturer would. Thus the court’s distinction does not seem to hold up.

Secondly, the defendant Bolar in Roche was not accused of using the patentee’s drug – Bolar obtained the drug from a foreign manufacturer.<sup>77</sup> Since this case provided the motivation for § 271(e)(1), there is no indication that Congress intended § 271(e)(1) to cover only the use of the patentee’s product (manufactured by the patentee) by a generic manufacturer in its testing process. The source of the drug is irrelevant since a party infringes the patent by using a drug or device that is claimed in the patent, regardless of who made it. Very often, the accused infringer might make the infringing product itself.

Third, a defendant’s subjective belief that it is or is not infringing a patent is not relevant to the question of infringement.<sup>78</sup> If a manufacturer begins to commercialize an infringing device, it will be liable for infringement

---

Drug, and Cosmetic Act.

<sup>74</sup>See § 515 of the FDCA.

<sup>75</sup>See Office of Technology Assessment, FEDERAL POLICIES AND THE MEDICAL DEVICES INDUSTRY, OTA-H-230, at 104 (Oct. 1984).

<sup>76</sup>See Peter B. Hutt & Richard A. Merrill, Food and Drug Law, Cases and Materials 752 (2nd ed. 1991).

<sup>77</sup>Roche, 733 F.2d at 860.

<sup>78</sup>A defendant’s subjective belief may be relevant to the question of willful infringement, which may, at a court’s discretion, result

whether it believed it infringed or not.

Fourth, the court seems to suggest that it is somehow difficult to know if a device infringes a patent, while the issue of whether a drug infringes a patent is clear. This seems to me to be backwards; mechanical devices are less abstract and easier for a patent attorney to analyze for infringement than chemical products. In any event, a party that wants to “know” if it is infringing should seek the advice of a patent attorney. Any reasonable manufacturer who markets a device with the intent that it will compete with a patented device will always, out of fear of treble damages, consult a patent attorney who will be able to tell the manufacturer whether it is infringing.

In light of the above, and of the Eli Lilly case, the distinction the court makes between drugs and devices seems to be incorrect. It is interesting that the court uses this distinction to justify its disregarding of much of the legislative history that is inconsistent with the conclusions it reaches.<sup>79</sup>

#### Defendant Ventritex's Motion for Summary Judgment on Grounds that § 271(e)(1) Covers its Activities

In ruling that § 271(e)(1) did cover Ventritex's activities, the court was again confronted with the issue of “purpose.” Specifically, the plaintiff wanted the court to consider non-infringing activities as evidence that not all of the defendant's infringing activities were done with the purpose of obtaining FDA approval.

The court first noted that non-infringing activities are not patent infringement. An inquiry under § 271(e)(1) is concerned only with acts that would otherwise be infringement; other acts need no protection. The plaintiff's argument was that these acts may be relevant inasmuch as they show the purposes behind the defendant's infringing acts.

The court decided again that the defendant's purposes were not relevant to the inquiry. First, the court points

---

in enhanced damages. See 35 U.S.C. § 284; *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, (7th Cir. 1983).

<sup>79</sup>See the court's treatment of this same legislative history in *Scripps* as discussed *supra*.

out that Congress used the word “uses” in the statute and that the words “uses” and “purposes” are not interchangeable. “Obviously, Congress is familiar with the word ‘purposes.’ If Congress had wanted the courts to focus on ‘purposes’ it probably would have selected that word instead of the substantially more awkward word ‘uses.’”<sup>80</sup> The selection of word “uses,” according to the court, meant that Congress intended an objective test, focusing on conduct rather than motive or intent.<sup>81</sup> The fact that Congress selected the phrase “reasonably related” to modify uses is further evidence of this intent because of that phrase’s association with objective standards.<sup>82</sup> The court also notes the fact that subjective tests are falling out of favor because of the difficulty of inquiring into motive and intent and the necessity of a jury trial to do so.<sup>83</sup>

The court also notes that other purposes are almost always present even in cases where a party would clearly be covered by § 271(e)(1). Simply put, manufacturers seeking FDA approval also have, as their primary purpose, the goal of making a profit. The fact that a party has as its purpose the ability to make a profit at some point should not disqualify a party from being afforded the protection of § 271(e)(1).<sup>84</sup>

With all of the above in mind, the court formulated the following oft-quoted<sup>85</sup> test:

Would it have been reasonable, objectively, for a party in the defendant’s situation to believe that there was a decent prospect that the “use” in question would contribute (relatively directly) to the generation of the kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product?<sup>86</sup>

Notice how much broader this test is than the one formulated in *Scripps*.<sup>87</sup> Under this test, one would assume

---

<sup>80</sup>755 F. Supp. at 1278.

<sup>81</sup>*Id.*

<sup>82</sup>*Id.* at 1279.

<sup>83</sup>*Id.*

<sup>84</sup>*Id.* at 1279-1280.

<sup>85</sup>See, e.g., *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 108 (D. Mass. 1998); *Abtox, Inc. v. Exitron Corp.*, 888 F. Supp. 6, 8 (D. Mass. 1995), *aff’d*, 122 F.3d 1019 (Fed. Cir. 1997); *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 205 (D.N.J. 1994).

<sup>87</sup>It should also be noted that the court in *Intermedics* never cites or distinguishes *Scripps*. While it is true that *Scripps* was a district court opinion that was in no way binding on the court in *Intermedics*, one might expect the court in *Intermedics* to at least acknowledge the *Scripps* opinion and either criticize or at least distinguish it.

the statute read, “for any use reasonably related to FDA approval.” The Scripps case would certainly have come out the other way under this test.

## The Federal Circuit’s Approach

The approach taken in the Intermedics case has won out. In both *Teletronics Pacing Systems, Inc. v. Ventritex, Inc.*<sup>88</sup> and *AbTox Inc. v. Exitron Corp.*,<sup>89</sup> the Federal Circuit adopted the reasoning in *Intermedics*. In both cases, the plaintiffs argued that because the defendant used information gained from activity related to FDA approval for other purposes (such as raising capital), the activity should not be covered by § 271(e)(1). In both cases, the court disagreed.

In *Teletronics*, the court pointed out that the economics of drug and device manufacturing require companies to do a lot of other things besides just seek FDA approval in order to market their drugs and devices. If Congress intended that after a patent expired, “immediate competition should be encouraged,”<sup>90</sup> it had to also intend for manufacturers to be able to raise money and do other things necessary to be able to start competing immediately. “It would strain credulity to imagine that Congress was indifferent to the economics of developing and marketing drugs and medical devices when it enacted § 271(e)(1).”<sup>91</sup>

Similarly, the court in *AbTox* interpreted § 271(e)(1) to allow other uses of information that was generated in activities that otherwise fall under the safe harbor. The court states that the statute “does not look to the

---

<sup>88</sup>982 F.2d 1520 (Fed. Cir. 1992).

<sup>89</sup>122 F.3d 1019 (Fed. Cir. 1997).

<sup>90</sup>H.R. Rep. No. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

<sup>91</sup>*Teletronics*, 982 F.2d at 1525.

underlying purposes or attendant consequences of the activity.”<sup>92</sup> Not only does the statute not look to purposes, those purposes are irrelevant even if, presumably, they indicate that the potential infringer has no intention of ever obtaining FDA approval, but has some other purpose in mind (such as taking sales and goodwill from the patentee). “As long as the activity is reasonably related to obtaining FDA approval, [the defendant’s] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield.”<sup>93</sup>

More Recently: Amgen

More recently, the court in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*<sup>94</sup> took a crack at the meaning of the statute. Amgen held patents on a genetically engineered hormone used for treating anemia. The defendants had produced the patented hormone and used it to conduct various tests that generated information that would be sent to the FDA. The plaintiff asserted that the defendant was also seeking regulatory approval overseas and designed some of those tests to meet other countries regulatory standards. Even though the information in those tests would be sent to the FDA and potentially used by the FDA to approve the defendant’s drug, the purpose of conducting them was, the plaintiff alleged, to get foreign regulatory approval and not to get FDA approval.

The court ruled that the activities were protected since intent and purpose were not part of the relevant inquiry under the statute. The court noted that the phrase used in the statute, “solely for uses reasonably related” is not equivalent to a more restrictive phrase that the plaintiff seemed to be arguing for: “use is solely for purposes reasonably related.”<sup>95</sup>

While this is certainly true, it is not clear that the test articulated in *Intermedics* is the equivalent of the statutory language either. That test drops the word “solely” altogether. The court rejects the plaintiff’s contention (and the *Scripps* opinion) that the word “solely” is rendered superfluous by the Federal Circuit’s interpretation in a

---

<sup>92</sup>*AbTox*, 122 F.3d at 1030.

<sup>93</sup>*Id.*

<sup>94</sup>3 F. Supp. 2d 104 (D. Mass. 1998).

<sup>95</sup>*Id.* at 107.



footnote.<sup>96</sup> Yet it provides no explanation of why this is so. Indeed, it is difficult to see how the Intermedics test would change if the statute were to read “for uses reasonably related” with “solely” omitted altogether.

The court notes that “many uses, such as animal testing, human clinical trials, or chemical composition analysis, may be related to FDA approval, yet be conducted for purpose other than, or in addition to, obtaining FDA approval.”<sup>97</sup> The court goes on to characterize Federal Circuit precedent as holding that “ulterior motives or alternate purposes do not preclude application of the section 271(e)(1) exemption.”<sup>98</sup> Neither the phrase “ulterior motives” nor the phrase “alternate purposes” can be found in the relevant Federal Circuit precedent. “Alternative uses” is a phrase found in the AbTox case.<sup>99</sup> Given this and other similarly minded courts’ views on the differences between the word “use” and the word “purpose,” I would think the court would be more careful. However, I will concede that the prior cases hold that intent and purpose are not relevant.

The use of the phrase “ulterior motives” arguably goes farther than any court before. “Ulterior motives” are bad motives, motives that are usually not condoned by the law. The word “ulterior” is defined in the American Heritage Dictionary as follows: “Lying beyond what is evident, revealed, or avowed, especially being concealed intentionally so as to deceive: an ulterior motive.”<sup>100</sup> (emphasis in original) The dictionary uses the phrase “ulterior motive” as illustrative of usage when the meaning is “concealed intentionally so as to deceive.” The court seems to be saying that as long as the defendant can meet the objectively reasonable test of Intermedics, it does not matter if the defendant is only using the possibility of eventually considering the seeking of FDA approval with deception, as cover to infringe a patent with impunity.

From Scripps to Amgen, the test went from “solely for uses reasonably related” to “it does not matter why you are doing it just as long as you can point to some way in which what you are doing arguably relates to some step in the process of obtaining FDA approval, whether or not you are or have any intent of seeking or even thinking

---

<sup>96</sup>Id at 108 n.3.

<sup>97</sup>Id at 107-108.

<sup>98</sup>Id at 108.

<sup>99</sup>Abtox, 122 F.3d at 1030.

<sup>100</sup>The American Heritage Dictionary of the English Language: Fourth Edition (2000).

about seeking such approval at some point in the future.” Similarly, the purposes of a parties activities are no longer relevant to a court’s inquiry even though the authors of the legislation wrote, “The purpose of [§ 271(e)(1)] is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement.” <sup>101</sup> (emphasis added)

Under the test articulated by the court in *Intermedics*, it seems that, as a general rule, anyone using a patented drug under an IND for any of the three phases of investigation would be shielded from an infringement action by § 271(e)(1). Phase 3 investigations generate the information needed to gain approval, which can certainly be considered the kind “of information . . . likely to be relevant in the processes by which the FDA would decide whether to approve the product.” <sup>102</sup> Phase 1 and 2 studies have a “decent prospect” of contributing to the generation of information needed for Phase 2 and 3 studies, respectively. Indeed, each phase is designed to contribute to the next. Since any activity under any of the phases must be done pursuant to an IND, all activities properly under an IND are covered by § 271(e)(1).

#### The IND Process<sup>103</sup>

“Almost all new drugs in the United States are developed by large pharmaceutical firms.” <sup>104</sup> Yet these large corporations often do not perform the clinic trials themselves. “Clinical investigations on new drugs are usually conducted by academic physicians working in university medical centers and by physicians in private practice. These investigations are frequently conducted on behalf of sponsoring drug firms, and the results may be published in

---

<sup>101</sup>H.R. Rep. No. 98-857(I), at 45 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2678.

<sup>102</sup>*Intermedics*, 775 F. Supp. at 1280.

<sup>103</sup>Much of the information on the IND process is taken from the FDA’s discussion of the proposed and final versions of the rules relating to the IND process, mainly 21 C.F.R. §§ 312 and 314. The proposed rules were issued in September 1983 and the final rule was issued in March 1987. This time period coincides with the *Roche* decision and the passage of § 271(e)(1). The *Intermedics* case followed a few years later. Accordingly, the facts, statistics, and reasoning in this rulemaking process are particularly relevant to the present discussion since they reflect the world in which § 271(e)(1) and its early interpretations were decided.

<sup>104</sup>Proposed New Drug, Antibiotic, and Biologic Drug Product Regulations, 48 Fed. Reg. 26720, 26723 (June 9, 1983).

the medical literature.”<sup>105</sup> The pharmaceutical company shepherds the drug through the stages of investigation from animal testing through the Phase 3 investigation. The IND’s necessary in this process are referred to as “commercial INDs.” The FDA defines a commercial IND as “an IND submitted by a pharmaceutical company or research center for the purpose of collecting safety and efficacy data necessary to gain marketing approval.”<sup>106</sup>

In addition to commercial IND’s, the FDA reviews “sponsor-investigator IND’s.”

The FDA defines a sponsor-investigator IND as an IND “submitted by an individual researcher, often associated with an academic institution, in order to conduct exploratory therapeutic research or to use the drug as a research tool.”<sup>107</sup> Consistent with the exploratory nature of these IND’s, sponsor-investigator IND’s “may involve either an unapproved drug or an approved drug for an unapproved use.”<sup>108</sup> The results of this exploration may be used to justify proceeding with the next stage of research. Or “if results from this research suggest marketing potential for the drug, further studies are usually conducted under the auspices of a commercial IND.”<sup>109</sup>

Another type of IND is the “treatment IND.” “The term ‘treatment IND’ applies to a request by a practicing physician to administer an unapproved drug primarily for treatment purposes within the investigational context.”<sup>110</sup>

Treatment IND’s are used when physicians wish to treat “patients with serious disease conditions who are not responsive to approved therapies, such as in the case with orphan drugs.”<sup>111</sup> This type of use is ordinarily allowed only after a Phase 2 investigation has been completed such that a good deal is known about the safety and dosage effects of the drug.<sup>112</sup>

Since sponsor-investigator IND’s and treatment IND’s are applied for by individuals or smaller institutions, they

---

<sup>105</sup>Id.

<sup>106</sup>Id.

<sup>107</sup>Id.

<sup>108</sup>Id.

<sup>109</sup>Id.

<sup>110</sup>Id.

<sup>111</sup>Id. at 26724.

<sup>112</sup>Id.

do not normally go through the entire three phase investigation process.<sup>113</sup> As one would expect, they are rarely used for Phase 3 studies, which require tremendous resources. They are, however, evaluated the same way that a commercial IND would be, depending on the phase.<sup>114</sup>

As of 1983 (just before the Hatch-Waxman Act), the FDA received “approximately 1,100 IND’s for new drug and biological products each year.”<sup>115</sup> Only about 25 percent of the IND’s received were commercial IND’s.<sup>116</sup> The largest percentage of IND’s were sponsor-investigator IND’s, which made up about 45 percent of all IND’s received.<sup>117</sup> The remaining 30 percent or so were treatment IND’s.<sup>118</sup> Since manufacturers of generic drugs presumably all qualify as large pharmaceutical companies, any IND’s they apply for would be commercial IND’s. Thus only a maximum of one quarter of all IND’s could potentially be applied for by manufacturers of generic drugs. Indeed, the percentage must be much smaller since all the pharmaceutical companies in the U.S. are presumably doing research on new drugs as well.

## IND’s and Approved Drugs

When the FDA approves a drug for use, it approves it for certain uses, i.e., to treat certain conditions in certain doses. The approved uses and dosages are set forth in the official labeling that accompanies the drug’s packaging.<sup>119</sup> As long as a manufacturer has FDA approval for a drug and ships the drug with the proper official labeling,

---

<sup>113</sup>Id at 26723.

<sup>114</sup>While it is true that some provisions of the Federal Regulations apply only to commercial IND’s, others only to sponsor-investigator IND’s, and others only to treatment IND’s, they are all examined the same way on the merits.

<sup>115</sup>Id at 26724.

<sup>116</sup>Id.

<sup>117</sup>Id.

<sup>118</sup>Id.

<sup>119</sup>See 21 C.F.R. § 201.5

it has satisfied its duty under the FDCA,<sup>120</sup> which ends at the moment of shipment into interstate commerce.<sup>121</sup>

Thus if a physician decides to prescribe that drug for a use or in a dosage that is not consistent with the official labeling, the manufacturer cannot be held liable for this potentially unauthorized use.

The FDA has taken the position that such “off label” use is not prohibited under the FDCA. “[T]he physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.”<sup>122</sup> The FDA views this type of use as “the practice of medicine” which it maintains is not subject to regulation under the FDCA.<sup>123</sup>

Despite the fact that physicians are not required to file an IND in such circumstances, they may wish to anyway.<sup>124</sup>

It may be in the best interests of a physician and the public that the therapeutic results and adverse reactions obtained by submitted to the FDA.<sup>125</sup> Often times physicians will be motivated by the moral and ethical issues surrounding the safety of the patients involved.<sup>126</sup> Other times, physicians will be partially motivated by the interest in advancing science, which may be facilitated by following the FDA's IND procedures.<sup>127</sup> In a related vein, physicians may be motivated by an interest in seeing an approved drug approved for a new use or dosage. Likewise, pharmaceutical companies may have an interest in seeing this happen and so might encourage physicians who are using a drug for a non-approved use to do so under an IND in order to advance the process of getting that drug approved for the new use.

---

<sup>120</sup>See FDCA § 505.

<sup>121</sup>See *United States v. Phelps Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946) (holding that violations after interstate shipment while products are being held for sale do not come within the jurisdiction of the Act.) The Miller Amendment of 1948 reversed this decision with respect to misbranding and adulteration, but not new drugs. Thus the decision still arguably applies the FDA's jurisdiction with respect to new drugs.

<sup>122</sup>Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration: Notice of Proposed Rule Making, 37 Fed. Reg. 16503 (August, 1972).

<sup>123</sup>See Proposed New Drug, Antibiotic, and Biologic Drug Product Regulations, 48 Fed. Reg. at 26733.

<sup>124</sup>See Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration: Notice of Proposed Rule Making, 37 Fed. Reg. 16503.

<sup>125</sup>*Id.*

<sup>126</sup>*Id.*

<sup>127</sup>*Id.*

A similar issue arises when “physicians, usually affiliated with academic institutions, seek to conduct ‘clinical investigations’ using marketed drugs, either to look for new uses or to use the drug as a research tool.”<sup>128</sup> The difference here is the physician’s motivation: research as opposed to treatment of his current patients. “FDA’s position has been, and continues to be, that such investigations are subject to [the IND requirements of the FDCA].”<sup>129</sup> However, the FDA has exempted from the IND requirements clinical investigations that do not present significant safety issues to patients. Thus if “the investigation does not involve a route of administration or dosage level or use in a patient population that significantly increases the risk associated with use of the drug product” and “the investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use, nor intended to be used to support any other significant change in the advertising or labeling for the drug,” then the use is exempt from the IND requirements.<sup>130</sup>

Whether a deviation from the approved use “significantly increases” the risks associated with a drug is left to the professional judgment of the physician.<sup>131</sup> A new dosage level (e.g. many times higher), new dosage forms (e.g. intravenously instead of a pill), or a new patient population (cancer drugs for non-cancer patients), are the types of new uses that the FDA suggests would present an increased risk.<sup>132</sup> In any event, a physician who wanted to be on the safe side and submit an IND for a clinical investigation that may not present “significant increases” in risk levels would presumably not be turned away by the FDA. That is, this exemption is permissive, not mandatory. And if there is any intent to use the information to support new labeling (that is, a new use or dosage), the clinical study should proceed under an IND.

---

<sup>128</sup>Proposed New Drug, Antibiotic, and Biologic Drug Product Regulations, 48 Fed. Reg. at 26733.

<sup>129</sup>*Id.*

<sup>130</sup>*Id.*

<sup>131</sup>*Id.*

<sup>132</sup>*Id.*

## Applying § 271(e)(1) to “Sham IND’s” and Subsequent Infringement Suits

Before examining specific types of cases that could involve § 271(e)(1) issues, it is useful to examine the various types of utility patents and how they are infringed.

### Types of Patents

In order for an invention to be patentable, it must fit into one of the four statutory classes of patentable subject matter.<sup>133</sup> The Patent Act provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”<sup>134</sup>

An application for a patent must include “one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”<sup>135</sup> It is the claims of the invention which set “the bounds to the grant which it contains. It is to the claims of every patent, therefore, that we must turn when we are seeking to determine what the invention is, the exclusive use of which is given to the inventor by the grant provided for in the statute.”<sup>136</sup>

Thus for a given invention, there may be many different ways to claim patent protection. For example, a manufacturer may claim a drug simply by claiming a product containing a certain chemical composition. The manufacturer may also claim a method of manufacturing the drug or a machine used to manufacture the drug.

---

<sup>133</sup>See *Kewanee Oil v. Bicron Corp.*, 416 U.S. 470, 483 (1974) (“no patent is available for a discovery, however useful, novel, and nonobvious, unless it falls within one of the express categories of patentable subject matter of 35 U.S.C. § 101.”)

<sup>134</sup>35 U.S.C. § 101.

<sup>135</sup>35 U.S.C. § 112.

<sup>136</sup>*Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917).

The manufacturer may claim the actual process by which the drug is made (a process claim) and/or the product made by a disclosed process (a product-by-process claim). The manufacture may also claim a method of using the drug to achieve some end, such as the treatment of a disease.

The scope of protection provided by the patent depends on the way in which protection is claimed. If the manufacturer claims the drug as a chemical composition, it can exclude others from making, selling, or using that drug altogether.<sup>137</sup> However, a manufacturer may only be able to claim a new method of using a drug and not the drug itself if the drug is old and well known. In such a case, anyone is free to make, use, or sell the drug for any purpose except for use in the claimed method. This type of protection is more limited in scope than a claim to the product itself, but may be very valuable nonetheless. It may be that the only current, practical use for the drug is to treat a certain disease by the claimed method. In such a case, the manufacturer is, for all practical purposes, afforded the same protection as if it owned a patent claiming the drug as a product. No one will want to make, use, or sell the drug for any purpose other than to be used in the claimed method, so anyone who does make, use, or sell it will do so in connection with an infringing use.

The manufacturer may be able to get quasi-patent protection for a drug in other ways. One such way would be to invent and claim an apparatus for delivering or administering a drug. If this apparatus were the only effective way to administer the drug, no one would be able to use the drug for its intended purpose without infringing the apparatus patent.<sup>138</sup> Similarly, inventing and claiming a method for using an apparatus to deliver a drug would provide quasi-patent protection for the drug if the method and apparatus were the only practical means by which to deliver the drug.

---

<sup>137</sup>35 U.S.C. § 154.

<sup>138</sup>Such a manufacturer would need to take care to avoid running afoul of the antitrust laws. For example, a manufacturer would not be permitted to force consumers to purchase the non-patented drug, presumably at a high price, from the manufacturer by refusing to sell the apparatus unless the consumer also bought the drug (a practice known as “tying”). However, the manufacturer is entitled to charge whatever price it wants for its patented device. In this way, the manufacturer could extract from the consumer the maximum amount that the consumer would be willing to pay to get the benefit of the drug; the same amount as if the manufacturer owned a patent to the drug itself.



Whom to sue for Infringement?

The issue of whether § 271(e)(1) would apply to a party's activities only arises, as a practical matter, if that party is sued for infringement. A party who will never be sued does not need to worry about whether his conduct constitutes infringement or fits into an exemption.

Economics drive a patent owner's decision-making process when it comes to whom to sue for infringement. The simple case is where a party owns a product patent to a drug claiming the drug itself and another party is making and selling that drug. The potentially infringing party is probably a large pharmaceutical company with millions or even billions of dollars in sales. Such a company is an obvious target since it can afford to pay damages and damages can be calculated with relative ease. However, this company is not the only party who is infringing the patent. The patient who uses the drug made and sold without the patent owner's permission infringes the patent. Luckily for the patient, it is not practical for the patent owner to sue every patient who has used an infringing drug. And even if it were, it is not clear what the damages would be or how they would be calculated.

The matter gets more complicated when the patent in question claims a method to treat a disease using a drug. In this case it is the doctor who directly infringes the patent because he actually uses the patented method.

There are many problems with suing doctors for infringing patents claiming methods of treatment. The first problem involves medical ethics. A method of treatment patent might prevent a patient from getting the best treatment because that treatment is too expensive or a license is not available, which may result in death. Doctors might feel bound to infringe the patent willfully to save the patient, resulting in treble damages. Secondly, if a doctor were to infringe a method of treatment patent and the patent owner were to sue him, the patent owner would have the unenviable task of trying to get a jury to find a "saintly" doctor (who probably just saved someone's life) liable for patent infringement.

Congress recognized many of these difficulties and passed 35 U.S.C. 287(c) in 1997.<sup>139</sup> This section provides:

---

<sup>139</sup>The motivation for passing this statute was a 1995 case in which an ophthalmologist brought an infringement action against another ophthalmologist for using his "stitchless incision" method of cataract surgery. Though unsuccessful, this suit provoked quite

“With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement . . . [the remedies provisions] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.”<sup>140</sup>

It is very important to notice that this provision does not declare that such activity “shall not be infringement” the way § 271(e)(1) does. It merely provides that a patent owner cannot recover damages or obtain an injunction against a doctor or related health care entity for infringement.<sup>141</sup>

Parties who directly infringe a patent are not the only ones who may be held liable for infringement. The law also “imposes liability upon persons who aid or abet direct infringement by others.”<sup>142</sup> This liability, known as contributory infringement, has two components. The first part is selling or offering to sell “a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention.”<sup>143</sup> The second component involves “knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.”<sup>144</sup> Additionally, there must be direct infringement by someone that the contributory infringer is contributing to. “There can be no contributory infringement of patent without fact or intention of direct infringement.”<sup>145</sup>

Thus the manufacturer who sells a drug to a doctor, knowing that the drug will be used to infringe a method of treatment patent is liable as a contributory infringer, but only if there are no other “substantial noninfringing

---

a bit of outrage. See *Pallin v. Singer*, Civ. No. 5:93-202, 1995 WL 608365 (D. Vt. May 1, 1995).

<sup>140</sup>35 U.S.C. § 287(c)(1).

<sup>141</sup>The statute gives the following non-exhaustive list of related health care entities: nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic. Note that this list does not include drug manufacturers.

<sup>142</sup>Donald S. Chisum, 5-17 Chisum on Patents § 17.01.

<sup>143</sup>35 U.S.C. § 271(c)(1).

<sup>144</sup>*Id.*

<sup>145</sup>*DeepSouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 32 L.Ed.2d 273, 92 S.Ct. 1700, 173 U.S.P.Q. 769 (1972), rehearing denied, 409 U.S. 902, 34 L.Ed.2d 165, 93 S.Ct. 94 (1972); and (superseded by statute on other grounds as stated in *Amstar Corp. v. Envirotech Corp.*, 823 F.2d 1538, 3 U.S.P.Q.2d 1412 (9th Cir. 1987)); and (superseded by statute on other grounds as stated in *Hughes Aircraft Co. v. United States*, 29 Fed. Cl. 197, 29 U.S.P.Q.2d 1974 (1993)); and (superseded by statute on other grounds as stated in *Subafilms, Ltd. v. MGM-Pathe Communications Co.*, 24 F.3d 1088, 94 C.D.O.S. 3381, 94 Daily Journal D.A.R. 6457, 30 U.S.P.Q.2d 1746 (9th Cir. 1994)).

uses” for the drug. In such a situation, the doctor is the direct infringer, even though he is not liable for this infringement because of § 287(c). The patent owner can recover the full amount of the damages from the contributory infringer since “[a] party that induces or contributes to infringement is jointly and severally liable with the direct infringer for all general damages.”<sup>146</sup>

While § 287(c) will not protect a contributory infringer, § 271(e)(1) will. A party may not be accused of contributing to infringement where the infringement is a result of the activity of a doctor that is using a patented device or process “solely for uses reasonably related” to gaining FDA approval. Such activity is not infringement, thus there is no direct infringement, and there cannot be contributory infringement.<sup>147</sup>

#### One Example of How a Party Might Use a “Sham IND” to Infringe a Patent

Imagine that a small pharmaceutical company has invented and patented a method for treating a certain condition. This method involves using an apparatus that the company has not patented but that has no other substantial, non-infringing use. The method also involves the use of old, well-known compounds. The non-patented apparatus is used to deliver these compounds.

The condition in question affects a relatively small percentage of the population. Unlike heart disease, cancer, HIV/AIDS, etc., there is not a tremendous amount of money to be made such that the large pharmaceutical companies would be interested in devoting major resources to this disease. The patented treatment is not a cure-

---

<sup>146</sup>Crystal Semiconductor Corp. v. TriTech Microelectronics International, Inc., 246 F.3d 1336, 1361 (Fed. Cir. 2001)

<sup>147</sup>Deepsouth, 406 U.S. 518.

all for this disease; rather it provides a small but not insignificant improvement compared to current treatments available.

The company has received FDA approval for treating a particular condition in a particular group of patients. The patent, however, covers a method that is useful to treat a variety of closely related diseases in a diverse group of patients. (For example, the method of treatment patent covers treating people who have breathing difficulties. The company has obtained FDA approval to use the method and apparatus to treat patients with asthma. The method would also be potentially useful to treat patients with emphysema.) The company can sell the apparatus to doctors who intend to use the apparatus to treat the wide variety of diseases (whether under an IND or not). Because of the patent, the company is able to sell the apparatus and compounds to doctors and patients at a price significantly above the cost of producing each unit. The company can charge whatever price it wants since no competitor can offer a lower price.<sup>148</sup> Because of this “legal monopoly” power, the company is able to recoup its research and development costs and maybe even make a substantial profit (e.g., several million dollars).

If a competitor wanted to enter the market, it would face two obstacles. The first would be FDA approval to sell the apparatus. This may not seem to be too significant a hurdle if the apparatus is relatively simple and/or the compounds involved are already approved for other uses. However, the FDA will not grant such approval until the second obstacle, the patent, expired.<sup>149</sup>

The competitor could avoid all these difficulties by utilizing the § 271(e)(1) safe harbor. One way to do this would be to require any physician who wanted to purchase the apparatus to have a sponsor-investigator or treatment IND. Many of the physicians who would want to use the patented product work in research hospitals and are quite familiar with the IND process and have probably applied for IND’s in the past. Once the IND is in place, the competitor company could sell the apparatus without being liable for infringement because it will be used

---

<sup>148</sup>The company would, presumably, charge the profit-maximizing price. That is, it would charge as much as it could without losing too many customers. Since total profits are equal to the profit per unit times the number of units sold, and the number of units sold will vary with the price, the company will select the price that leads to the greatest total profits.

<sup>149</sup>35 U.S.C. § 271(e)(2).

for a “use” reasonably related to seeking FDA approval. Another way to get the benefit of the § 271(e)(1) safe harbor would be to for the company to file for an IND itself. It could then sell to any doctor it wanted as long as it conditioned the sales on participation in the clinical study.

These types of IND’s could be called “Sham IND’s” because the IND holder did not obtain the IND for the purpose of investigating a new drug. The IND was obtained in order to gain the benefit of the safe harbor under § 271(e)(1) for otherwise commercial sales activity.

The competitor company is not free to charge whatever price it wants for the apparatus or compounds sold pursuant to an IND. Under FDA regulations, the sponsor of a clinical trial “may not commercialize an investigational drug by charging a price larger than that necessary to recover costs of manufacture, research, development, and handling of the drug.”<sup>150</sup> If the sponsor of a clinical trial wants to charge for the drug at all, it must get FDA approval and must explain why charging is necessary.<sup>151</sup> For a smaller company, it may be impossible to finance the cost of an investigation without being able to charge, especially if the apparatus or compounds are expensive. In such a case, one would expect the FDA to allow the manufacturer to charge.

In order to prevent its commercialization, FDA regulations also prohibit the promotion of an investigational drug before it is approved.<sup>152</sup> The regulations also prohibit prolonging an investigation after the results of the investigation appear to establish sufficient data to support an application for FDA approval.<sup>153</sup> This prevents a company from continuing to sell the drug for investigational purposes once the investigation is completed.

The House Report accompanying § 271(e)(1) makes clear that Congress did not intend for § 271(e)(1) to allow the unlimited commercial sale of investigational drugs. However, Congress did see the need for commercial sales of the investigational drug to investigators. “This section does not permit the commercial sale of a patented drug by the party using the drug to develop [information related to FDA approval], but it does permit the commercial

---

<sup>150</sup>21 C.F.R. § 312.7(d)(3).

<sup>151</sup>21 C.F.R. § 312.7(d)(2).

<sup>152</sup>21 C.F.R. § 312.7(a).

<sup>153</sup>21 C.F.R. § 312.7(c).

sale of research quantities of active ingredients to such parties.”<sup>154</sup>

## Why a Company Might Want to Use a “Sham IND”

Since a company is prohibited from making a profit from selling an investigational drug, why would a company file a “sham IND” in order to sell the drug? One reason is that they might be able to make a profit despite the prohibition against doing so. The regulations permit the seller of an investigational drug to recover costs of manufacture, research, development, and handling of the drug.<sup>155</sup> The company may be able to play a lot of accounting games with the numbers corresponding to these expenses. For example, the company may have many researchers working on many different projects at the same time. It may be difficult to allocate the salary of a given researcher to the expenses involved with each project on a perfectly proportional basis. A slight over-allocation to the investigational drug would result in a cost on paper higher than the actual cost to the company. The difference in the two costs would be profit.

Similarly, the company may need to build a new machine to manufacture the apparatus or drug. The machine, once built, may be used for another project in the future. Or it may be sold in the future. How would a company account for this? If the company simply allocated the entire cost of the machine to the expense of creating the investigational drug, it would be overstating costs and making a profit equal to the difference between the overstated and actual costs.

Even if a company could and did allocate costs proportionally, it may still be better off by selling the investigational drug at cost than it would be without those sales. Any increase in efficiency or synergy due to the new drug's

---

<sup>154</sup>H.R. Rep. No. 98-857(I), at 45 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2678.

<sup>155</sup>21 C.F.R. § 312.7(d)(3).

manufacture would be captured as profit. This can be illustrated as follows. Say, for example, that a company used to sell only Drug A. Upon deciding to sell an equal amount of an investigational drug with the same costs as Drug A, the company's expenses would increase; it would now be selling twice as many drugs. But it would not need to double its factory space. Some machines could be used for both drugs. Though the number of employees would increase, the company would probably not need to double the size of the management and support staff (they would not need two payroll clerks, two receptionists, etc.). Thus the company would realize efficiencies and synergies.

In this example, the cost of producing the two drugs would rightfully be allocated 50/50. Say, for example, the sales of Drug A were \$100 and the costs were \$50, leaving \$50 in profit. After deciding to produce the investigational drug, say the new cost to produce both drugs would be \$80. The costs attributable to the investigational drug would be \$40 (\$80 split 50/50), thus that drug could be sold for \$40. The new total sales would be \$140. With total costs of \$80, the company's profit would be \$60.

Even if a company would make little or no profit by selling the investigational drug, it may have other, less noble, reasons for wanting to do so. One such reason might be to injure a competitor. The company would set a price somewhere near its actual costs (maybe with a small profit as discussed above). By selling at a lower price, the company would lure away the customers of its competitor, the patent owner. The competitor would have to lower its price to match the lowest price or it would eventually lose most or all of its customers. The competitor would now be selling at a price that does not enable it to recover the costs it incurred as the first to develop this new treatment. Instead of being handsomely rewarded for its successful innovation, the competitor is ruined.

This competitor likely competes in other areas as well. By taking away its profits, the competitor would have

fewer resources to use to develop new products in the future. The competitor might go out of business altogether, leaving more market share for the company that is left. With fewer competitors, the company might be able to charge a higher price for all of its products.

This company represents the worst kind of Holmesian bad man. It may have no intention of seeking FDA approval for its product once the patent expires. Maybe this is because the process of seeking FDA approval is too expensive. Maybe by the time the patent expires, the method of treatment will be obsolete (a very realistic possibility). Or maybe the company will eventually seek FDA approval for treating one particular species of the condition, knowing it will then be able to sell its product for use in treating any condition a doctor wants it for.

This company may be achieving the Congressional goal of having competition as soon as the patent expires,<sup>156</sup> but it is also able to achieve competition before the patent expires and destroy much of the value of a patent. It also harms the patent system since a patentee may not even be able to recover the expenses involved in creating the patented product or method.

## Trying to Stop a “Sham IND” Holder

It is not clear that a court would be able to stop a “sham IND” holder from selling the patented product with damages or an injunction. Since the test under *Intermedics* does not allow the court to look to purposes, a potential plaintiff would be prevented from introducing evidence regarding purpose. The court could not inquire into why the potential infringer sought an IND. The court could not inquire into whether the potential infringer intended to eventually apply for FDA approval. The potential infringer would only need to show that it had an IND and

---

<sup>156</sup>H.R. Rep. No. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.



that its use of the patented product was pursuant to that IND.

If an IND provides a shield against an infringement action, the next logical question for a patentee would be whether it could attack the validity of the IND. The patentee might try to get the FDA to terminate the IND. Federal Regulations provide that IND's may be terminated for a variety of reasons.<sup>157</sup> Many of these have to do with safety concerns, failures to report information, or with deviations from the terms of the IND. The Regulations also provide that an IND may be terminated if "[t]he drug is being promoted or distributed for commercial purposes not justified by the requirements of the investigation or permitted by § 312.7."<sup>158</sup>

A patentee may want to attack the decision to allow an IND by arguing that the investigation is not likely to generate scientifically useful results that will advance the approval process. The FDA assesses "the scientific quality of the clinical investigations and the likelihood that the investigations will yield data capable of meeting statutory standards for marketing approval" in IND's for Phase 2 and 3 studies.<sup>159</sup> However, the FDA does not assess these factors for Phase 1 studies, instead focusing only on assuring the safety of the patients.<sup>160</sup> The FDA relies on Institutional Review Boards to make sure that investigators are not doing studies that will produce no scientifically useful results and thereby endanger patients' lives and waste everyone's time for no good reason.

It is not at all clear how a patentee might be able to bring a suit challenging any of the above. The patentee could try to get a hearing, but an IND, like an NDA, is a private license and the FDCA only permits the applicant to request a hearing.<sup>161</sup> The patentee could try to sue the infringer directly, alleging a violation of the FDCA, but there is no private right of action in the FDCA.<sup>162</sup> The patentee could bring suit under the Administrative Procedure Act, but would have to argue that the FDA's actions in allowing the IND or failing to terminate it were arbitrary and capricious.<sup>163</sup> This showing is difficult to make. The court would have to find "a clear error in

---

<sup>157</sup>21 C.F.R. § 312.44.

<sup>158</sup>21 C.F.R. § 312.44(b)(1)(v).

<sup>159</sup>21 C.F.R. § 312.22(a).

<sup>160</sup>*Id.*

<sup>161</sup>See Hutt, *supra* note 76, at 1270.

<sup>162</sup>*Florida ex rel. Broward County v. Eli Lilly & Co.*, 329 F. Supp. 364 (S.D. Fla. 1971).

<sup>163</sup>5 U.S.C. § 706 (2)(A).

judgment” on the part of the FDA.<sup>164</sup> The court is not allowed to concern itself with the wisdom of the agency action or substitute its judgment for that of the agency.<sup>165</sup> It is also not clear that the patentee is “harmed” in a way that would entitle it to standing to bring such a suit.<sup>166</sup>

The patentee’s best chance might be to file an infringement action and then reply to the inevitable § 271(e)(1) defense by challenging the defendant’s assertion that the use is reasonably related to seeking approval despite the IND. The patentee would have to argue that because the IND is a sham, the use is not reasonably related to seeking FDA approval. This might convince the judge to allow evidence on whether the IND is a sham. On the other hand, the judge might be likely to defer to the “wisdom of the agency action” and be wary of “substituting his judgment” for that of the FDA. After all, the FDA has procedures for monitoring IND’s and terminating them if they are being used for commercial purposes. If the FDA has not terminated an IND, it must either think there is at least some potential scientific benefit or be completely incompetent and blind to the IND holder’s abuse of the system. The court may not want to, or be able to, determine which is the case.

## Is the Courts’ Broader Reading of § 271(e)(1) a Good Thing?

Whether one views the present broad reading of § 271(e)(1) as a positive development probably depends on the individual’s views about the general purposes of intellectual property laws. The current state of the law would probably not sit well with someone who approaches the patent system with a “natural rights” perspective. If inventors are supposed to be entitled to reap the reward of the fruits of their labor and innovation, then a law

---

<sup>164</sup>Norwich Eaton Pharmaceuticals, Inc. v. Bowen, 808 F.2d 486, 493 (6th Cir. 1987) (quoting *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971)).

<sup>165</sup>*Id.*

<sup>166</sup>These issues of standing, private rights of action, and suits under the APA are very complex and beyond the scope of this paper.

which allows that reward to be lost in certain situations would be unjust.

But the “natural rights” approach to patents (and other types of property law) has fallen out of favor over the years. Even the Constitution declares that the purpose of any patent laws enacted by Congress was to be the promotion of the progress of the useful arts. The intellectual property clause does not read, “To ensure that inventors receive the rewards to which they are entitled. . . .” Indeed, the courts have long recognized that patents are an affirmative grant by Congress and that Congress is free to limit the rights granted as it pleases.<sup>167</sup> If Congress were to decide that scientific progress is best promoted by granting a very broad infringement exemption for any activity that remotely resembles research activity, it would certainly be within its constitutional mandate to do so. The wisdom of creating such an exemption is a separate question. If this exemption eliminated the incentives for investing in research because of the uncertainty of being able to recover this investment, it would clearly be a mistake.

Rather than eliminate incentives, it is possible that a more limited exemption, like the current exemption under § 271(e)(1), would hamper progress only in certain areas. The development of products with major markets that are unaffected by a small amount of research-related competition would be unaffected by the exemption. On the other hand, innovation in areas where the available rewards are limited and the need for more innovation is great could be harmed. These areas that are ripe for continued innovation would be filled with more potentially exempt research-related activities. The ability to reap a reward may be delayed until a problem is completely solved and a patent can be obtained on a product or method that requires no further research. The wisdom of this type of system for promoting scientific progress is questionable.

A more interesting question is whether Congress intended to create as broad an exemption to infringement as has been created by § 271(e)(1). Congress imagined the normal case under § 271(e)(1) would be a generic drug

---

<sup>167</sup>See, e.g., *Mast, Foos & Co. v. Stover Mfg. Co.*, 177 U.S. 485, 494 (1900) (Congress, having created the monopoly, may put such limitations upon it as it pleases.).

company preparing to enter the market for a drug that has big sales. Its use of the patented drug for testing would have an imperceptible effect on the market. Congress apparently did not consider the case where the market is such that investigational use (under an IND) might account for a significant portion of the market or where investigational use might be an alternative to the use of the patented drug in an approved treatment.

As discussed above, the legislative history suggests that Congress had in mind the more limited issue of the availability of generic drugs. The House Report had in mind the case where “the only purpose of the experiments is to seek FDA approval for the commercial sale of the drug after the patent expires.”<sup>168</sup> The Roche case had discussed the limited scope of the “experimental use” exemption and Congress could have decided to expand the “experimental use” exemption beyond its common law scope to include all kinds of experimentation with patented inventions. Instead, Congress chose to limit 271(e)(1) to uses related to FDA approval, suggesting a decision to create a very narrow exemption.

Another question is whether Congress decided to create an exemption that would cause economic harm to patent holders. The House Committee on Energy and Commerce did not think that § 271(e)(1) would have “any adverse economic impact on the patent owner’s exclusivity during the life of a patent.”<sup>169</sup> Likewise, the House Judiciary Committee wrote, “The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial.”<sup>170</sup> It seems that any interpretation of § 271(e)(1) that does adversely impact patent holders would be inconsistent with Congress’ intent.

Of course, Congress could have written § 271(e)(1) using narrower language, tailored to the generic drug situation, if it wanted to avoid the present difficulties. On the other hand, Congress may not have foreseen the possibility

---

<sup>168</sup>H.R. Rep. No. 98-857(I), at 45 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2678.

<sup>169</sup>H.R. Rep. No. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

<sup>170</sup>H.R. Rep. No. 98-857(II), at 8 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2692.

of the present interpretation of the statute when they wrote it, especially given the fact that the court in *Scripps* was able to interpret the statute in a manner consistent with the Congressional intent as stated in the House Reports.

In the end, will companies that manage to secure IND's have total immunity from patent infringement suits for all time? Probably not. Someone will undoubtedly get "too cute" with the whole process and invite a judicial or even congressional response. Hopefully, Congress will address the issue and clarify exactly what kind and breadth of "experimental use" exemption it intends to grant in order to best promote the progress of the useful arts.